

Focus Issue of the MonthIndian Pharmaceutical Industry

Why is it the focus issue? ...

We have been reading a lot about the pharmaceutical industry by way of global mergers and their implications on their affiliates here, new frontiers of opportunities in biotechnology, expanding horizons in AIDS research, opening up of health insurance, reduction in span of control on drugs, consolidation strategies through acquisitions, co-marketing, contract manufacturing and licensing arrangements. With so much happening in the sector, we thought it would be prudent to examine the ramifications of such events on the pharmaceutical industry which at present is going through a transitional phase due to change in business dynamics.

The Global Scenario.....

The global pharmaceutical industry presently valued at \$300bn is expected to grow at a CAGR of 8% over the next five years. As per data available from IMS Health pharmaceutical sales in 13 key markets around the world grew 10% during FY01. The degree of consolidation is evident from the fact that the top ten pharmaceutical companies account for 45% of the global market in CY2000 as against 27% during CY1993. Merger of parent companies have triggered restructuring and have inflated the size of their Indian affiliates besides leading to margin expansion and widening of therapeutic width and product reach.

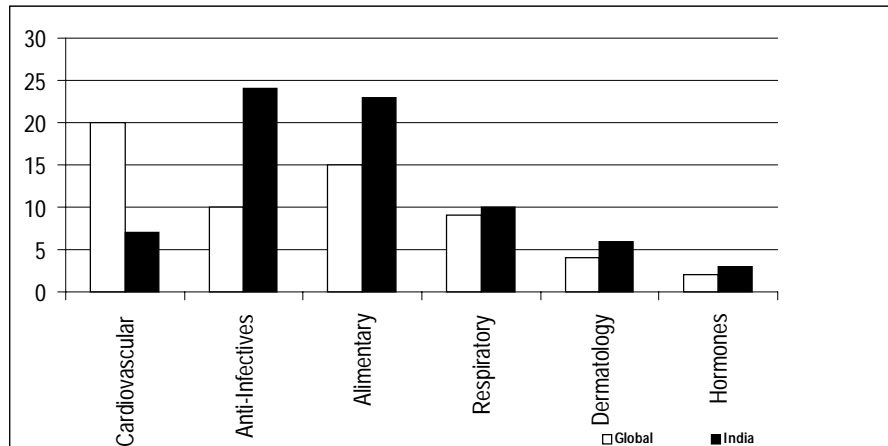
The Indian Scenario.....

The Indian Pharmaceutical market valued at \$3.3bn in FY2000 is placed sixth in terms of volume but is placed fifteenth in terms of value in the global market. The domestic per capita drug expenditure is only \$3 compared to \$190 in the US, \$100 in the UK and \$7 in China. We believe that the low penetration level of medical insurance is mainly responsible for the low level of drug consumption in India. Presently, a patient has to pay for his treatment first and then recover costs from the insurance company, thereby discouraging people from going in for medical insurance. However, with the entry of private insurance companies, this payment mode is set to change which in turn would expand the healthcare market in the country.

India's drug consumption profile has started following global patterns.....

Indian scenario following global patterns: Tropical nature of disease profile in India had oriented drug consumption pattern in the country towards anti-infectives and vitamins. As a matter of fact, antibiotics formed 24% of the total drug consumption in 1999. However changing demographics has altered this scenario towards life style drugs in cardiovascular, psychiatry, neurology, gynaecology, and diabetology segments more in line with the western countries.

Therapeutic Profile of India v/s Global (% share of sales)





Fragmentation itself would lead to consolidation within the industry....

Emerging trends in the domestic scene:

Buying out brands is the best way to expand therapeutic width and capture market share without the burden of additional manpower. Indian companies have been scouting for brands in order to spur top-line growth and we expect this trend to continue going forward which in turn would alter the ranking of the companies in the retail branded formulations market. Brand acquisitions seem to be the logical answer to consolidation within the highly fragmented pharmaceutical sector in India.

Co-marketing provides market coverage to new molecules.....

Co-marketing arrangements tend to expand the size of the market and MNC subsidiaries in India have found co-marketing arrangements with domestic pharmaceutical companies attractive since it enhances product visibility which in turn helps in expanding the size of the market. The problem arises only when a third large player enters the same market with its generic version at a much lower price.

MNC subsidiaries in India have underperformed their domestic counterparts.....

Indian companies are moving up the value chain from generics to novel drug delivery systems and to new drug discoveries and they have the capabilities to make positive announcements in R&D by way of new molecule discoveries, license fees, milestone payments etc. This explains the rationale for share prices of MNC subsidiaries to have underperformed their domestic counterparts. MNC's face constraints in terms of new product launches and pricing of new products whereas the domestic companies are hedged to some extent against a slowdown in the industry largely due to exports.

Impact of reduction in span of control in the new drug policy on drug companies.....

Impact of the Impending New Drug Policy on the Industry: We have observed in our studies that since price controls on drugs began to be relaxed in 1995, product prices did increase by about 25% on an average during the first year of decontrol. As in the case of the 1995 price decontrol, we do not expect such price increases to sustain beyond a two-year time frame. Let us examine the potential beneficiaries of pruning down the number of drugs under price control.

% under Price Control	Glaxo	Knoll	Hoechst	EMerck
% Top 15 brands	25	35	40	40
% Domestic Sales	60	65	55	70

Source: LKP Estimates

One must note that presently about 30% of drugs under price control belong to mass categories like anti-infectives, pain management and vitamins. We believe that for the new drug policy to be effective, it should allow drug companies to plan for the growth of their brands without the inherent fear of ad hoc changes in ceiling prices. The National Pharmaceutical Pricing Authority (NPPA) has powers to bring any drug under its ambit and also has the powers to recommend a ceiling price for a drug, which has been brought under its ambit.

Profitability for companies in the regulated pharmaceutical industry is largely a function of their presence in high-growth therapeutic segments and the extent of DPCO (Drug Price Control Order) coverage in their product portfolio. Among the domestic players, Cipla and Ranbaxy have close to 40% of their domestic formulation sales under price control. We expect Ranbaxy Labs, Cipla, Glaxo and Hoechst Marion to be the beneficiaries of the new drug policy.

TRIPs compliant patent laws would help increase investments in R&D.....

Absence of patent protection has been a major factor against MNCs increasing R&D investment in India. Trade Related aspects of Intellectual Property rights (TRIPs) compliant patent laws would increase investments in research and technological development especially investments by multinationals through the FDI route.

India is committed to implementing product patent systems by January 01, 2005. During this transition period, Exclusive Marketing Rights (EMR) would be granted if the required conditions are satisfied.

New Frontiers of Opportunities:

Expanding horizons in AIDS research.....

New avenues in AIDS drugs : The Mumbai-based Cipla was the focus of attention after it signed a pact with the Brussels based NGO-Medicines sans Frontieres for the supply of its anti-AIDS triple combination retro-viral drug for as much as \$350. The Pretoria High Court which began hearing arguments in a lawsuit filed by 42 MNCs against the South African government's proposal to review its drug licensing laws, specifically as regards the possibility of allowing generic suppliers to enter the market. After three years in court, these 42 companies withdrew their case in April this year and the monopoly of these pharmaceutical majors in the South African market is numbered.

Domestic companies like Cipla now feel that a system whereby a company pays a fixed royalty to the patent holder, similar to what South Africa has agreed upon, would safeguard the interests of our country and has asked the registrar of patents in South Africa to grant it compulsory licencing for the entire range of anti-AIDS drugs that the company manufactures.

New frontiers of opportunities.....

Genomics provide the emerging opportunity: Pharmaceutical companies are best equipped to exploit those remarkable genes provided by Genomics viz the process of creating gene based drugs starting from gene sequencing to analysis and interpretation to drug development. To create a new medicine, an understanding of how genes regulate proteins is essential in order to identify the genetic source of a disease. Proteomics- studying the structure of a protein as a result of its genetic code does exactly this. Genomics and Proteomics research is expected to increase the 500 odd biological targets at present to more than ten times that amount.

Bioinformatics- the study of genes and proteins using information technology is a \$3 billion market worldwide and about \$50 million in India though very little of this comes from genomics and proteomics. Genomics research offers tremendous potential and little wonder that US based Merck & Co has lapped up Rosetta for \$620m and is eyeing Gene Logic.

Dr Reddy's Labs and Wockardt offer the best play in biotechnology.....

Large domestic pharmaceutical companies are strengthening their R&D skills through combinatorial chemistry and high-throughput screening, plant metabolites, pre-clinical toxicology, molecular biology and leveraging on strengths in organic synthesis. Domestic companies like **Dr Reddy's Labs** and **Wockhardt** are working on recombinant DNA platforms, cell culture and molecular biology and have plans to manufacture therapeutic proteins for use as vaccines and anti-virals. We believe that these two companies are well-equipped to capitalise on their efforts in the field of biotechnology.

Chiral Chemistry offers a window of opportunity.....

Emerging Trends in Chiral Chemistry: Many drugs are chiral compounds, which exist as a mixture of two mirror-image forms known as isomers. Most drugs administered to treat diseases are transformed or metabolised within the body into a variety of related forms or metabolites, some of which have therapeutic benefits. Improved Chemical Entities (ICE) are proprietary, single isomer versions that may offer therapeutic advantages over existing drugs. Since these are variants of proven drugs, the inherent risk of failure in ICE is lower and the clinical trial frame may be shortened compared to conventional chemical entities.

Domestic companies like Cipla are using chiral compounds as a means of extending the life of a patent. Cipla is targeting four chiral drugs-Rsalbutamol, RFormoterol, ESomeprazole and Levocetirizine.



Outlook and Valuation for the Pharmaceutical Industry:

Domestic companies with an R&D pipeline have the ability to generate positive earnings surprise.....

Internationally most of the pharmaceutical companies are currently trading close to 30x2001E earnings except for Aventis, Sanofi and Pfizer which trade in the higher range. Similarly international generic companies which are integrated like Ivax, Mylan, Watson and Teva trade close to 30x2001E earnings except for Andrx which trades in the higher range.

We prefer large companies with the ability to beat market growth rates and improve market share....

We have enclosed an Annexure (Refer to Appendix IV) to highlight the current valuations of Indian pharmaceutical companies. Among Indian companies we continue to prefer leading domestic companies like **Dr Reddy Labs** and **Cipla** due to their strong branded formulation franchise and innovative marketing capabilities. These companies have a dominant position in the domestic market which provides them with a competitive edge in a market characterised by rapid consolidation. We believe that the premium valuations are justified considering the management ability to generate positive earnings surprises on account of their R&D pipeline. The wide ownership of these stocks by itself reflects the built in expectations from the management.

We continue to prefer top rung companies with the ability to beat market growth rates and are positive on companies like **Ranbaxy Laboratories**, **Sun Pharmaceuticals** and **Wockhardt** as we believe that these companies are likely to emerge much stronger than their peers going forward.

We prefer MNC companies who successfully launch global products into India at the same time....

MNC subsidiaries in India do not conduct independent research in India and most of them have separate 100% subsidiaries operating in the country. We believe that introduction of global products in India along with their global launch and their pricing levels are the key issues which would drive valuations of MNC subsidiaries in India. To put things in perspective we believe that the valuation of MNC subsidiaries would not follow the valuation of parent companies abroad. Most of the MNC's are marketing companies and the risk of issues like transfer pricing would ensure that MNC's with a separate 100% subsidiary enjoy a lower discounting.

Our top pick in the MNC segment is **Hoechst Marion Roussel**, to be renamed Aventis Pharmaceuticals since the company has launched its entire range of global products into India and the focus in India continues to be in full alignment with that of its parent abroad.

We prefer only those second rung companies that have the ability to grow products into large brands.....

As far as the other second rung pharmaceutical companies are concerned, we believe that consolidation activities within the sector would force them to become part of the universe comprising of the larger companies. Absence of initiatives on the R&D front and inability on the part of these companies to develop and nurture large brands have ensured that most of these companies quote close to 5x FY02E earnings. However it must be mentioned that if such companies are able to create brands which could emerge as leaders in certain therapeutic segments and improve market share by beating sector growth rates they are likely to get noticed even among the large number of listed pharmaceutical companies.